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LAHIVE & COCKFIELD, LLP/THE MATHWORKS One Post Office Square Boston, MA 02109-2127				
			EXAMINER SIMS, JASON M	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 03/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/783,624

**Applicant(s)**

PAXSON ET AL.

**Examiner**

JASON M. SIMS

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/16/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments, filed 11/16/2007, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 11/16/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 45-47 in the response filed 11/16/2007, which have been acknowledged and entered.

Claims 1-22 and 45-47 are the current claims hereby under examination.

#### ***Specification***

The objection to the specification has been withdrawn because of applicant's amendments to the specification.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/16/2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

#### ***Claim Rejections - 35 USC § 101-Maintained***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22 and 45-47 are drawn to a process and/or system. A statutory process or a system that embodies a statutory process must include a final resulting

step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). Furthermore, a system w/out any physical limitations, which recites only "instructions" type of limitations encompasses a program, per se. A program, per se, is not statutory subject matter. The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-22 and 45-47 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. For the instant claims there is a step that recites "generating as output dynamic behavior of the biological system." However, it is unclear as to where the output data is going. For example, the output may be input data for another simulation prior to being available to a user, which in that case the step would remain reading on non-statutory subject matter for failing to produce a tangible result. Furthermore, the amended step of "a storage component for storing the graphical model of the biological system" does not necessitate the storage of the final resulting method step. Therefore, the storage component for storing the graphical model does not necessarily store the resulting data of the improved simulation. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or to a user, or by including a final resulting step of a physical transformation, if such wording is supported by the instant specification.

***Response to Arguments:***

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Applicant's arguments filed 11/16/2007 have been fully considered but they are not persuasive.

Applicant argues that the amended step of "a storage component for storing the graphical model of the biological system" causes the instant claims to now being drawn to statutory subject matter.

Applicant's arguments are not found persuasive. It is appreciated that applicant's have amended their claims in an attempt to overcome the instant rejection of claims under 35 USC 101. However, the amended step of "a storage component for storing the graphical model of the biological system" does not necessitate the storage of the final resulting method step. Therefore, the storage component for storing the graphical model does not necessarily store the resulting data of the improved simulation. The storage component may just store the created graphical model of the biological system, but not store simulation data. Moreover, there is a step that recites "generating as output dynamic behavior of the biological system." However, it is unclear as to where the output data is going. For example, the output may be input data for another simulation prior to being available to a user, which in that case the step would remain reading on non-statutory subject matter for failing to produce a tangible result.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has newly added claims 45-47, which comprise new limitations such as annotating the graphical model in response to a user requesting to add annotations to the model that are provided by the user and support for said new limitations have not been pointed to by the applicant nor found by the examiner. Therefore, the newly added claims have been found to comprise new matter.

***Claim Rejections - 35 USC § 102***

***Response to arguments:***

Applicant's arguments, filed 11/16/2007, with respect to the rejection of claims under 35 USC 102 (b) using the Kurata reference have been fully considered and are persuasive because of applicant's arguments and amendments. Therefore the rejection has been withdrawn.

***The following rejections are being newly applied and have been necessitated by amendment:***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-22 and 45-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Sauro et al. (2003).

Sauro et al show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface (GUI) to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior (figure 11). In figure 11 and figure 12 of Sauro et al, the elements of modeling component having a GUI providing means for accepting user input via a tool palette to generate a block diagram of a plurality of related chemical reactions that make a biological system. The figure also depicts an analysis environment displaying the dynamic behavior of the biological system, and a simulation engine. Sauro et al show that the dynamic behavior of the system is modeled using a stochastic computational model (p 355 and 364). Sauro et al. discloses the capabilities of simulating the dynamic behavior along with the ease of annotating and editing within the JDesigner environment. Furthermore, the JDesigner environment works well with the Jarnac environment to build an easy to use systems biology development environment.



Claims 1-5, 8-11, 14-17, 20-23, 26-29, and 32-35 rejected under 35

U.S.C. 102(b) as being anticipated by Hucka et al (Pacific Symposium on Biocomputing Vol. 7, p.450-461, 2002).

The claims are directed to a system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior.

Hucka et al show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior (figures 1 and 2). Hucka et al describe jdesigner, a software providing a GUI to accept user commands and data (sect. 5.2). Jdesigner provides a tool palette aiding in the construction of the of a block diagram model, as is seen in figure 1 (figure 1 and p. 452). As shown in figure 1, the modeling component includes a block diagram of related chemical reactions. Hucka et al show that the simulation engine, generates the dynamic behavior of the system using a stochastic computational model (p. 459, sect 5.8-9).

### ***Double Patenting-Maintained***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 and 45-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/783,628. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to

display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,628 are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 and 45-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/783,552. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn to a system, computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to

display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,552, are directed to a system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

*John S. Brusca 19 February 2008*  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER